

**Office Of The Secretary Of Defense (OSD)
Deputy Director Of Defense Research & Engineering
Deputy Under Secretary Of Defense (Science & Technology)
Small Business Innovation Research (SBIR)
FY2008.2 Program Description**

Introduction

The Deputy Under Secretary of Defense (Science & Technology) SBIR Program is sponsoring the Defense Health Program Biomedical Technology theme in this solicitation.

The Army, Navy, and Air Force are participating in the OSD program this year. The service laboratories act as our OSD Agent in the management and execution of the contracts with small businesses. The service laboratories, often referred to as a DoD Component acting on behalf of the OSD, invite small business firms to submit proposals under this Small Business Innovation Research (SBIR) program solicitation. In order to participate in the OSD SBIR Program this year, all potential proposers should register on the DoD SBIR website as soon as you can, and should follow the instruction for electronic submittal of proposals. It is required that all bidders submit their proposal cover sheet, company commercialization report and their firm's technical and cost proposal form electronically through the DoD SBIR/STTR Proposal Submission Website at <http://www.dodsbir.net/submission>. If you experience problems submitting your proposal, call the help desk (toll free) at 1-866-724-7457. You must include a Company Commercialization Report as part of each proposal you submit; however, it does not count against the proposal page limit of 25 pages. Please note that improper handling of this form may result in the proposal being substantially delayed. Information provided may have a direct impact on the review of the proposal. The DoD SBIR Proposal Submission Website allows your company to come in any time (prior to the proposal submission deadline) to edit your Cover Sheets, Technical and Cost Proposal and Company Commercialization Report.

We WILL NOT accept any proposals that are not submitted through the on-line submission site. The submission site does not limit the overall file size for each electronic proposal, there is only a 25 page limit. However, file uploads may take a great deal of time depending on your file size and your internet server connection speed. If you wish to upload a very large file, it is highly recommended that you submit prior to the deadline submittal date, as the last day is heavily trafficked. You are responsible for performing a virus check on each technical proposal file to be uploaded electronically. The detection of a virus on any submission may be cause for the rejection of the proposal. We will not accept e-mail submissions.

Firms with strong research and development capabilities in science or engineering in any of the topic areas described in this section and with the ability to commercialize the results are encouraged to participate. Subject to availability of funds, the DUSD(S&T) SBIR Program will support high quality research and development proposals of innovative concepts to solve the listed defense-related scientific or engineering problems, especially those concepts that also have high potential for commercialization in the private sector. Objectives of the DUSD(S&T) SBIR Program include stimulating technological innovation, strengthening the role of small business in meeting DoD research and development needs, fostering and encouraging participation by minority and disadvantaged persons in technological innovation, and increasing the commercial application of DoD-supported research and development results. The guidelines presented in the solicitation incorporate and exploit the flexibility of the SBA Policy Directive to encourage proposals based on scientific and technical approaches most likely to yield results important to DoD and the private sector.

Description of the OSD SBIR Three Phase Program

Phase I is to determine, insofar as possible, the scientific or technical merit and feasibility of ideas submitted under the SBIR Program and will typically be one half-person year effort over a period not to exceed six months, with a dollar value up to \$100,000. We plan to fund 3 Phase I contracts, on average, and downselect to one Phase II contract per topic. This is assuming that the proposals are sufficient in quality to fund this many. Proposals should concentrate on that research and development which will significantly contribute to proving the scientific and technical feasibility of the proposed effort, the successful completion of which is a prerequisite for further DoD

support in Phase II. The measure of Phase I success includes technical performance toward the topic objectives and evaluations of the extent to which Phase II results would have the potential to yield a product or process of continuing importance to DoD and the private sector, in accordance with Section 4.3.

Subsequent Phase II awards will be made to firms on the basis of results from the Phase I effort and the scientific and technical merit of the Phase II proposal in addressing the goals and objectives described in the topic. Phase II awards will typically cover 2 to 5 person-years of effort over a period generally not to exceed 24 months (subject to negotiation). Phase II is the principal research and development effort and is expected to produce a well defined deliverable prototype or process. A more comprehensive proposal will be required for Phase II.

Under Phase III, the DoD may award non-SBIR funded follow-on contracts for products or processes, which meet the component mission needs. This solicitation is designed, in part, to encourage the conversion of federally sponsored research and development innovation into private sector applications. The small business is expected to use non-federal capital to pursue private sector applications of the research and development.

This solicitation is for Phase I proposals only. Any proposal submitted under prior SBIR solicitations will not be considered under this solicitation; however, offerors who were not awarded a contract in response to a particular topic under prior SBIR solicitations are free to update or modify and submit the same or modified proposal if it is responsive to any of the topics listed in this section.

For Phase II, no separate solicitation will be issued and no unsolicited proposals will be accepted. Only those firms that were awarded Phase I contracts, and have successfully completed their Phase I efforts, will be invited to submit a Phase II proposal. Invitations to submit Phase II proposals will be released at or before the end of the Phase I period of performance. The decision to invite a Phase II proposal will be made based upon the success of the Phase I contract to meet the technical goals of the topic, as well as the overall merit based upon the criteria in section 4.3. DoD is not obligated to make any awards under Phase I, II, or III. DoD is not responsible for any money expended by the proposer before award of any contract. For specifics regarding the evaluation and award of Phase I or II contracts, please read the front section of this solicitation very carefully. Every Phase II proposal will be reviewed for overall merit based upon the criteria in section 4.3 of this solicitation, repeated below:

- a. The soundness, technical merit, and innovation of the proposed approach and its incremental progress toward topic or subtopic solution.
- b. The qualifications of the proposed principal/key investigators, supporting staff, and consultants. Qualifications include not only the ability to perform the research and development but also the ability to commercialize the results.
- c. The potential for commercial (defense and private sector) application and the benefits expected to accrue from this commercialization.

In addition, the OSD SBIR Program has a Phase II Plus Program, which provides matching SBIR funds to expand an existing Phase II contract that attracts investment funds from a DoD acquisition program, a non-SBIR/non-STTR government program or Private sector investments. Phase II Plus allows for an existing Phase II OSD SBIR contract to be extended for up to one year per Phase II Plus application, to perform additional research and development. Phase II Plus matching funds will be provided on a one-for-one basis up to a maximum \$500,000 of SBIR funds. All Phase II Plus awards are subject to acceptance, review, and selection of candidate projects, are subject to availability of funding, and successful negotiation and award of a Phase II Plus contract modification. The funds provided by the DoD acquisition program or a non-SBIR/non-STTR government program must be obligated on the OSD Phase II contract as a modification prior to or concurrent with the OSD SBIR funds. Private sector funds must be deemed an "outside investor" which may include such entities as another company, or an investor. It does not include the owners or family members, or affiliates of the small business (13 CFR 121.103).

The Fast Track provisions in section 4.0 of this solicitation apply as follows. Under the Fast Track policy, SBIR projects that attract matching cash from an outside investor for their Phase II effort have an opportunity to receive interim funding between Phases I and II, to be evaluated for Phase II under an expedited process, and to be selected for Phase II award provided they meet or exceed the technical thresholds and have met their Phase I technical goals, as discussed Section 4.5. Under the Fast Track Program, a company submits a Fast Track

application, including statement of work and cost estimate, within 120 to 180 days of the award of a Phase I contract (see the Fast Track Application Form on www.dodsbir.net/submission). Also submitted at this time is a commitment of third party funding for Phase II. Subsequently, the company must submit its Phase I Final Report and its Phase II proposal no later than 210 days after the effective date of Phase I, and must certify, within 45 days of being selected for Phase II award, that all matching funds have been transferred to the company. For projects that qualify for the Fast Track (as discussed in Section 4.5), DoD will evaluate the Phase II proposals in an expedited manner in accordance with the above criteria, and may select these proposals for Phase II award provided: (1) they meet or exceed selection criteria (a) and (b) above and (2) the project has substantially met its Phase I technical goals (and assuming budgetary and other programmatic factors are met, as discussed in Section 4.1). Fast Track proposals, having attracted matching cash from an outside investor, presumptively meet criterion (c). However, selection and award of a Fast Track proposal is not mandated and DoD retains the discretion not to select or fund any Fast Track proposal.

Follow-On Funding

In addition to supporting scientific and engineering research and development, another important goal of the program is conversion of DoD-supported research and development into commercial (both Defense and Private Sector) products. Proposers are encouraged to obtain a contingent commitment for follow-on funding prior to Phase II where it is felt that the research and development has commercialization potential in either a Defense system or the private sector. Proposers who feel that their research and development have the potential to meet Defense system objectives or private sector market needs are encouraged to obtain either non-SBIR DoD follow-on funding or non-federal follow-on funding, for Phase III to pursue commercialization development. The commitment should be obtained during the course of Phase I performance, or early in the Phase II performance. This commitment may be contingent upon the DoD supported development meeting some specific technical objectives in Phase II which if met, would justify funding to pursue further development for commercial (either Defense related or private sector) purposes in Phase III. The recipient will be permitted to obtain commercial rights to any invention made in either Phase I or Phase II, subject to the patent policies stated elsewhere in this solicitation.

Contact with DoD

General informational questions pertaining to proposal instructions contained in this solicitation should be directed to the topic authors and point of contact identified in the topic description section. Proposals should be electronically submitted. Oral communications with DoD personnel regarding the technical content of this solicitation during the pre-solicitation phase are allowed, however, proposal evaluation is conducted only on the written submittal. Oral communications during the pre-solicitation period should be considered informal, and will not be factored into the selection for award of contracts. Oral communications subsequent to the pre-solicitation period, during the Phase I proposal preparation periods are prohibited for reasons of competitive fairness. Refer to the front section of the solicitation for the exact dates.

Proposal Submission

Proposals shall be submitted in response to a specific topic identified in the following topic description sections. The topics listed are the only topics for which proposals will be accepted. Scientific and technical information assistance may be requested by using the SBIR/STTR Interactive Technical Information System (SITIS).

It is required that all bidders submit their proposal cover sheet, company commercialization report and their firm's technical and cost proposal form electronically through the DoD SBIR/STTR Proposal Submission Website at <http://www.dodsbir.net/submission>. If you experience problems submitting your proposal, call the help desk (toll free) at 866-724-7457. You must include a Company Commercialization Report as part of each proposal you submit; however, it does not count against the proposal page limit of 25 pages. Please note that improper handling of this form may result in the proposal being substantially delayed. Information provided may have a direct impact on the review of the proposal. The proposal submission website allows your company to come in any time (prior to the proposal submission deadline) to edit your Cover Sheets, Technical and Cost Proposal and Company Commercialization Report. We **WILL NOT accept any proposals which are not submitted through the on-line**

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The following pages contain a summary of the technology focus areas, which are followed by the topics.

Defense Health Program Biomedical Technology Focus Area

The Department of Defense is aggressively pursuing unified Force Health Protection and Deployment Health strategies to protect Service members and their families from health hazards associated with military service. Toward that end, DoD is undertaking technology development programs that save lives and promote healthy individuals, units and communities while improving both force morale and warfighting capabilities.

The operational force is exposed to health threats throughout the operational continuum, from CONUS fixed facilities (garrison, base, ashore) through deployment, employment, and redeployment. DoD is developing policy and procedures to assess occupational and environmental health threats for all locations.

When Force Health Protection capabilities are fully implemented, commanders will have a more complete view of potential health threats. Integration of assessments from health databases and other assessments from intelligence (e.g., about land mines, directed enemy fire, fratricide) and safety (e.g., about injuries, vehicle accidents, explosives, aviation mishaps) will provide a framework for identifying future medical technology capabilities necessary for Force Health Protection.

Ensuring the health of the force encompasses several key capabilities:

- To mobilize, deploy and sustain medical and health support for any operation requiring military services;
- To maintain and project the continuum of healthcare resources required to provide for the health of the force;
- To operate in conjunction with beneficiary healthcare; and
- To develop training systems which provide realistic rehearsal of emergency medical and surgical procedures and unit-level medical operations.

These capabilities comprise an integrated and focused approach to protect and sustain DoD's most important resource—its Service members and their families—throughout the entire length of service commitment.

The Office of the Secretary of Defense believes that the small-business community can be effective in developing new technology-based approaches to needs in force health protection. Three broad capability areas of particular interest are tools and techniques for near real-time surveillance of the health threats and health status of the Force, for epidemiology research, and for delivery of health education and training. These are described in more detail below:

- **Health Surveillance Planning and Decision Support Tools:** Tailorable and targeted software applications that are integrated into the Military Health System's backbone of installed information systems are the essential enabling technology for surveillance. Applications in the areas of decision support tools, data and knowledge management, information visualization technologies including geospatial tools, and artificial intelligence-based appliques for essential analyses are needed. It is expected that the applications would produce a comprehensive system of risk based assessments, predictions, and courses-of-action utilizing epidemiological, intelligence, environmental exposure, and health information concerning deployed forces. The applications should also allow for predictive modeling of medical readiness scaleable from individuals to the aggregated Force, given such data streams as reported real and somatic symptoms.
- **New Methods to Monitor Health Status and Clinical Laboratory Data:** Monitoring of health status during deployments is necessary to determine etiologic factors of deployment related health change. Data and information analysis tools are needed to collect and harmonize disparate data and information sources and to provide health status surveillance pre- or post-injury to medical information consumers within and outside of military medical channels. Health monitoring should be for a limited set of indicators, and should yield an unambiguous interpretation of health status. Projects are required to have a strong biological basis and be sensitive to changes in health status based on either real-time measurements from warfighters in an operational environment, clinical laboratory data sources, and/or recorded in-patient or out-patient or trauma registry data.
- **Medical Training and Learning Tools:** Developing and maintaining skills among the personnel of the Military Health System is an important aspect of deployment health. Advanced distributed learning,

simulation-based training and other computer-based training technology should enable all health-care personnel to plan, respond and manage the future medical missions, and should assist medical professionals to maintain clinical knowledge and skills. Tools that can be extended to use by the general military population for proactive preventive medicine are desirable. Tools should be based on existing medical and allied health knowledge, should be universally accessible, should allow for unlimited practice, and should be SCORM-compliant in content and in delivery modalities.

The Defense Health Program Biomedical Technology topics are:

- OSD08-H01 New Methods to Monitor Health Status and Clinical Laboratory Data (Navy)
- OSD08-H02 An Internet-Based Rehabilitation Program for Warriors with Hearing Loss and Auditory Processing Disorders Secondary to Blast and Traumatic Brain Injuries (Army)
- OSD08-H03 Automated Patient Safety Ordering System (Army)
- OSD08-H04 Micro Games for Proactive Preventive Medicine (AF)
- OSD08-H05 Determining Biomarkers of Occult or Emerging Disease for Predictive Modeling (AF)
- OSD08-H06 Interactive Cognitive Interface and Health Monitoring System (Army)
- OSD08-H07 Automated Knowledge Structuring of Medical Charts Data (Army)
- OSD08-H08 Augmented Reality Systems for Training Health Care Providers (Army)
- OSD08-H09 Advanced Distributed Learning in Support of the Maintenance of Certification (MOC) of Surgical Skills (Army)
- OSD08-H10 Diamond-like Carbon Coatings on Polymers (Army)

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OSD08-H01	New Methods to Monitor Health Status and Clinical Laboratory Data
OSD08-H02	An Internet-Based Rehabilitation Program for Warriors with Hearing Loss and Auditory Processing Disorders Secondary to Blast and Traumatic Brain Injuries
OSD08-H03	Automated Patient Safety Ordering System
OSD08-H04	Micro Games for Proactive Preventive Medicine
OSD08-H05	Determining Biomarkers of Occult or Emerging Disease for Predictive Modeling
OSD08-H06	Interactive Cognitive Interface and Health Monitoring System
OSD08-H07	Automated Knowledge Structuring of Medical Charts Data
OSD08-H08	Augmented Reality Systems for Training Health Care Providers
OSD08-H09	Advanced Distributed Learning in Support of the Maintenance of Certification (MOC) of Surgical Skills
OSD08-H10	Diamond-like Carbon Coatings on Polymers

OSD SBIR 082 Topic Descriptions

OSD08-H01 TITLE: New Methods to Monitor Health Status and Clinical Laboratory Data

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Employ new physical measurement methods and analysis to determine human health status before, during, and after deployments by using a limited set of physiological indicators. Provide hardware derived data and analysis that unambiguously determines etiologic factors related to changes in general health status. Design this epidemiological system using technology that has a strong biological basis and is sensitive to changes in health status based on real-time measurements from warfighters in operational environments, clinical laboratories, and in-patient/out-patient or trauma registries. Pre- and post injury measurements will be used to gauge and direct recovery strategies.

DESCRIPTION: New methods of collecting physiological data in both hospital and field settings are needed for the next generation of health status monitoring devices. Traditional methods using ECG for heart rate (HR) and HR variability (HRV) analysis, auscultatory or oscillometric blood pressure (BP) cuffs, chest plethysmographs or chest trans-thoracic electrode systems for respiration rate (RR) data, and other techniques have often been combined into systems that involve separate functional parts attached to various parts of the body, usually by a nest of wires. ECG, for instance, generally requires at least two adhesive-backed electrodes and their attached wires that must be protected during use. They are prone to noise from nearby electrical disturbance due to electromagnetic pulses and bursts or even engine noise and may be dangerous in some situations due to the breakdown of skin resistance caused by the conductive adhesive. Traditional BP cuffs are well developed and provide etiologic data when used periodically, but require large batteries if portable and used often. To be used in critical situations over extended periods, their use is restricted to every fifteen minutes because the arm needs time to recover. Ideally, a single, wire-free (and wireless) device is sought that: measures a minimal set of etiologic vital signs in a continuous manner; operates autonomously using small batteries for days or longer; provides critical warnings to attending personnel due to deteriorating medical conditions or trends in a patient; is small, light and easy to install; provides easy access to stored information in the form of an automatic on-board medical chart; is installable by minimally trained personnel; works seamlessly through transport from the field, to hospitals, and surgery suites without removal; and could be used during rehabilitation or at home. The device and software could be used by a Corpsman or Medic to quickly determine if a Marine or Soldier has or is developing deteriorating health status. For injured or wounded personnel, the device would provide next generation medical techniques that take advantage of algorithmic driven control in: automatic infusion pump systems for smoother and faster resuscitation of trauma patients; restricted fluid therapy to avoid over hydrating the patient; and fluid therapy to prevent drops in BP during hemorrhaging procedures. All these and others now in development will require near beat-to-beat BP (B3P) along with HR, RR, possibly oximeters and others. While arterial catheters (A-lines) provide B3P, installation of these devices is not practical except by using highly trained personnel and they are generally prohibited during the transportation of casualties. A truly non-invasive B3P system would eliminate almost all other dual uses of A-Lines because equivalent data are available with venous catheters, which can be used in the field, can be installed by lesser trained personnel, and can be used during transport. Multi-parameter, non invasive, continuous vital signs monitoring could be useful in diagnosing sleep disorders or sampling the BP variability for early signs of heart problems, which is not possible with conventional BP monitors. Records of individual variations in physiological parameters before and after trauma, before and after training, fatigue, or psychologically distressing experiences could aid in identifying and treating these conditions.

PHASE I: Propose a multiparameter system and show that the measured set of physiological parameters is sufficient to unambiguously determine changes in health status due to some physical condition, determined by the contractor. Provide demonstration, examples, or rationale for applicability to deployment related health problems. Give scientific rationale and/or demonstration that the proposed method would apply to field measurements, transport measurements, and all necessary clinical uses.

PHASE II: Develop a complete system with hardware and software that could be used by medical or non-medical personnel in all stages of medical surveillance related to deployment issues, trauma management, health status measurement, medical transport, hospitalization, surgery, and recovery.

PHASE III: Monitoring of health status will be tested at training facilities such as Camp Pendleton and the Navy Hospital. The system will be marketed for applications such as civilian emergency, trauma care, health management of first responders, home monitoring, and clinical medicine.

REFERENCES:

1. Westwood, JD editor, Medicine Meets Virtual Reality 15; "The structure of the radial pulse - a novel noninvasive ambulatory blood pressure device". IOS Press: 40-42 (2007).
 2. Vyas, M, et.al. "Augmentation Index and Central Aortic Stiffness in Middle-Aged to Elderly Individuals", American Journal of Hypertension (AJH), 2007; 20:642-647.
 3. Pauca, AL, et.al., "The second peak of the radial artery pressure wave represents aortic systolic pressure in hypertensive and elderly patients", British Journal of Anaesthesia (BJA) 92 (5): 651-7 (2004).
 4. Kwon, KW, "Building a Better Blood Pressure Monitor: A Novel Noninvasive Device That Permits Continuous Monitoring", American Society of Nephrology" (Renal week 2006, November 14-19, San Diego, CA).
- KEYWORDS: Monitoring, vital signs, physiological parameters, non-invasive, clinical, laboratory.

OSD08-H02 TITLE: An Internet-Based Rehabilitation Program for Warriors with Hearing Loss and Auditory Processing Disorders Secondary to Blast and Traumatic Brain Injuries

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop, implement and evaluate a home-based, interactive, adaptive, internet tool designed to employ sensory-based modalities in efforts to rehabilitate the communicative capabilities of blast casualties and traumatic brain injury victims.

DESCRIPTION: This topic is designed to create, assess and validate an automated educational program designed to rehabilitate the communicative capabilities of both blast casualties and victims of traumatic brain injury. This interactive tool is designed to employ both auditory and visual modules. This self-administered tool should be of benefit to service members experiencing hearing loss and central auditory processing disorders associated with blast and traumatic brain injuries. Such a program should be cost-effective (home-based) and acceptable to the demographic of today's soldier (internet-based and adaptive).

The signature injury of combat continues to be improvised explosive device (IED)-induced blast injury. One of the major consequences of such injuries is tympanic membrane (TM) perforation with consequent hearing loss. In fact, the TM is the structure most injured by blast (DePalma, Burris, Champion & Hodgson, 2007) and a recent observation (Xydakis, Bebart, Harrison, Conner & Grant, 2007) suggests a strong association between barotrauma-related TM perforation and TBI among the blast-injured in Iraq. Of 860 wounded in action service members evaluated at the Army Audiology and Speech Center at Walter Reed Army Medical Center between March 2003 and October 2005, more than half (433) had blast-related injuries and a third of those had TM perforations. Among those presenting with otologic symptoms, 52% had sensorineural hearing loss, 21% had conductive hearing loss, and 27% had mixed hearing loss (Chandler, 2006). Clearly, the prevalence of permanent communication impairment resulting from hearing loss and TBI is a major consequence of the injuries being sustained by members of the armed forces engaged in the global war on terrorism (GWOT).

Clinical observations have revealed a growing number of returning service members who exhibit significant communication complaints in the absence of hearing loss. It is thought that blast-induced TBI results in damage to central auditory system structures resulting in problems processing rapid speech or understanding speech in less than optimum listening conditions. For this population, conventional hearing aids will not provide any benefit. Even among those service members with hearing loss (and without TBI), the use of hearing aids does not guarantee maximum restoration of communicative function. In fact, post-fitting rehabilitation programs have demonstrated improved self-perceived benefit among hearing aid users when compared to using hearing aids without a structured training program (e.g. Hnath Chisolm, Abrams & McArdle, 2004). The design of these rehabilitative programs

range from those that are counseling-based to those that involve specific auditory training exercises. Recent post-fitting rehabilitation strategies have focused on interactive, adaptive computer programs that are utilized in the privacy of the patient's home.

This internet-based tool is intended to improve communication performance in those situations that present the greatest problems for the hearing impaired and where the benefits of hearing aids tend to be most limited in their application. Individuals with TBI, even in the absence of hearing loss, tend to have difficulties in those same situations (communicating in background noise, listening to rapid speech, and communicating in the presence of competing speakers). In these difficult situations, listeners make use of many non-auditory cues, primarily from the visual modality, to enhance their ability to understand speech. One of the shortcomings of many of these home-based computer programs is that they focus exclusively on the auditory signal. Evidence suggests that the effective use of visual cues combined with the auditory information can have a significant positive impact on speech recognition in adverse listening environments (Grant, Walden, and Seitz, 1998). Such visual and auditory-visual integration training may be particularly critical for those service members suffering from central auditory processing disorders associated with TBI.

PHASE I: In phase I, the parameters of the interactive internet-base tool will be determined and clearly defined, (i.e. the identification and differentiation of associations between listening versus hearing as related to the importance of effective communication). These parameters will include plasticity-based and behaviorally oriented modules which incorporate both visual and auditory modalities. This phase will include the development of a prototype of the decision tool which will be inclusive of the parameters identified above regarding critical skills such as hearing and listening. The model must identify and differentiate between a minimum of four sets of parameters. The proof of concept will be accomplished through the successful integration of these parameters into the internet-based, interactive tool.

PHASE II: In this phase, the efforts achieved during phase I will be exploited and further refined. Communication strategies will be established based on the application of the parameters articulated in the development of the phase I prototype. Quantifiable performance measures will be developed. The self-paced tool must be inclusive of a continual feedback system to maximize patient motivation and minimize fatigue. The input must be verifiable through such concepts as "datalogging". The program will be designed to adapt as the patient's critical communicative skills progress. This will be coupled with real-time capabilities for monitoring a patient's status and obtaining analysis of the program's reliability and validity via quantifiable performance measures.

PHASE III: The intent of this tool is to provide a venue through which communication skills may be maximized for auditorily impaired individuals. The interactive internet tool has direct application as a cost effective casualty treatment regimen for re-deploying Soldiers with communication impairments. Moreover the tool provides similar application to non-militarily impaired patients. The tool will offer significant benefits to nursing home residents, to communicatively impaired school students and patients of healthcare treatment facilities. The tool expands provisions for rehabilitation to the indigent, who is least capable of affording extensive rehabilitation services. This Tool will serve as a critical instrument for the audiologist's arsenal of educational materials. Not only will this program allow the user to advance in skill as appropriate, thereby perfectly tailoring a treatment regime, it will enable the professional to tap into secure, real-time monitoring capabilities of the 21st century.

REFERENCES:

1. Chandler D (2006). Blast-related ear injury in current U.S. military operations. *The ASHA Leader*, 11(9):8-9,29.
2. DePalma RG, Burris DG, Champion HR, Hodgson MJ (2007). Blast injuries. *New England Journal of Medicine*, 352(13): 1335-1342.
3. Grant, KW, Walden, BE, Seitz, PF (1998). Auditory-visual speech recognition by hearing-impaired subjects: Consonant recognition, sentence recognition, and auditory-visual integration. *J. Acoust. Soc. Am.* 103(5):2677-90.
4. Hnath-Chisolm T, Abrams H, McArdle R (2004). Short- and long-term outcomes of adult audiological rehabilitation. *Ear & Hearing*, 25(5):464-477.
5. Sabes JH, Sweetow RW (2007). Variables predicting outcomes on listening and communication enhancement

(LACE) training. International Journal of Audiology, 46(7):374-83.

6. Sweetow RW, Sabes JH (2006). The need for and development of an adaptive Listening and Communication Enhancement (LACE) Program. Journal of the American Academy of Audiology, 17(8):538-58.

7. Xydakis MS, Bebart VS, Harrison CD, Conner JC, Grant GA (2007). Tympanic-membrane perforation as a marker of concussive brain injury in Iraq. Letter to the Editor, New England Journal of Medicine, 357(8):830-831.

KEYWORDS: Interactive, Internet, Audiology, Traumatic Brain Injury, Communication Strategies, Blast Injuries, sensory based modalities, Central Auditory Processing Disorders, Adaptive, Hearing Loss.

OSD08-H03 **TITLE:** Automated Patient Safety Ordering System

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop a patient safety feature to Computerized Physician Order Entry systems (CPOE) and Pharmacy Data Transaction System (PDTS) that monitors and facilitates 1) drug reconciliations between outpatient and admission, between admission and discharge and between levels of care; 2) drug contraindication screening using patient-specific data; 3) medication screening for therapeutic duplication and treatment failure; 4) dosage checking; and 5) corollary orders needed.

DESCRIPTION: The military has a CPOE system and a Pharmacy Data Transaction System, and the VA has a different system. Our systems must be integrated and therefore may be changing in the future. In addition, the military is in the process of updating its transaction system, ordering system and inventory system. Recently, the Food and Drug Administration has provided electronic drug labels on their web site (Daily Med) that is continually being updated and is available to all users. This SBIR topic is focused on design and development of a prototype capability to monitor electronic medical records and facilitate 1) drug reconciliations between outpatient and admission, between last order sets and discharge and between levels of care; 2) drug contraindication screening using patient-specific data (labs, other meds, co-morbidities, allergies, age, GFR, LFT); 3) medication screening for therapeutic duplication; 4) dosage checking; and 5) corollary orders needed. The system should work with any CPOE and PDTS systems (such as monitoring for HL7 messages). Knowledge for contraindications and laboratories needed for patient-specific data per drug should come from public domain data, minimizing the cost of updating the knowledge. The prototype design should contain the following elements:

- 1) For drug reconciliation: view of discharge medications from prior admission and list of active medications from outpatient records to facilitate assembling list of current medications. Ability to flag or highlight admission order if dosage does not match last medication order.
- 2) For drug contraindication, develop novel method to map web available drug label's contraindication, drug-interaction and warning elements with patients ICD9 codes (you may have to map ICD9 codes to MedDRA codes), problem list, allergy, age, last laboratory and vital signs (BMI) and current medication list as indicated. It is important that the system developed does not require uniquely writing the logic for each medication for which a rule will be applied (such as checking for K, not giving medication if K low, or Cr increased for only one medication). Therefore an editor system that allows one to build new rules is needed. Some labels will only say that drug causes increase in Creatinine or decrease in K and the system would have to have a general rule to monitor these labs and provide the lab trends (last 3 values) prior to dosing or dispensing/ordering. The system must be able to auto-display relevant laboratory test result or trend in test results for patient when physician selects a medication order with a lab monitoring requirement. System can associate medications and relevant lab tests for automatic display with a medication order.
- 3) To monitor for therapeutic duplication/failure, that is to monitor (data mine) for greater than expected change or cancellation orders in same therapeutic class and multiple drugs in same therapeutic class and provide a warning of possible treatment failure.
- 4) Dosage checking is to pull from label max dose given age and other parameters, drug level in labs, and GFR/renal dosing some of which may be rule based also guidance for medication-related laboratory testing, drug-pregnancy checking, and drug-disease contraindication checking, and monitor drug levels (e.g., based on PT or drug level).

- 5) Corollary orders, to pull from labels information that labs requiring monitoring and ensuring orders are written (Ability to have recommended secondary orders display with the primary order (e.g., lab test to titrate dosing) as well as per national guidelines.
- 6) Monitor medications for indications map to guidelines.

PHASE I: Develop and demonstrate a prototype of a patient safety system that could interact with a CPOE and PDTS and EMR to incorporate the 5 features discussed in this topic. Discuss a generalized way that rules can be applied and that modification of the rules remains with the users. This will minimize requiring multiple rules and the users having the ability to edit rules and write new rules easily. Discuss and demonstrate importation of knowledge and updates of knowledge and how it will be handled. Demonstrate a data mining tool to suggest treatment failure and possible overdose. Demonstrate how system will individualize treatment for patient by allergies, age, weight, GFR, and liver functions, concomitant medications and co-morbidities will occur for dosing and ordering labs.

PHASE II: Develop and validate a system to interact with the DoD EMR, CPOE system and PDTS to improve patient safety. System must be tested with users and maintain a way to dampen or heighten warnings so it does not interfere or overwhelm the end user. The system will not be able to be integrated into the DoD system for demonstration, however, a sample of the patient data will be provided for demonstration. Must be able to demonstrate performance measures that system can detect individualized labs, treatment duplications, treatment failures with high enough accuracy not to be intrusive. A clinical acceptance of system must be demonstrated.

PHASE III: This system would be applicable to the DoD, the VAH and commercial enterprise if it were easy to use, inexpensive, improved outcomes and patient safety and demonstrated cost effectiveness and safety as a key feature. If it could be added as a safety feature to any system, it would have wide applicability and if much of the knowledge was public domain from FDA and NIH websites, the cost of updating knowledge would be less than paying an enterprise to maintain that knowledge. In addition if users had control of modifying the generalizability rules and warnings, and an editor to write their own rules, it would benefit the organization by improving acceptability.

REFERENCES:

1. Crit Pathw Cardiol. 2007 Sep;6(3):106-16. Links Multidisciplinary rounds (MDR): an implementation system for sustained improvement in the American Heart Association's Get With The Guidelines program. Ellrodt G, Glasener R, Cadorette B, Kradel K, Bercury C, Ferrarin A, Jewell D, Frechette C, Seckler P, Reed J, Langou A, Surapaneni N; Multidisciplinary Rounds Team.
2. J Am Med Inform Assoc. 2007 Jan-Feb;14(1):29-40. Epub 2006 Oct 26. Links. Medication-related clinical decision support in computerized provider order entry systems: a review. Kuperman GJ, Bobb A, Payne TH, Avery AJ, Gandhi TK, Burns G, Classen DC, Bates DW.
3. J Am Med Inform Assoc. 2007 Jan-Feb;14(1):25-8. Epub 2006 Oct 26. Links. A pragmatic approach to implementing best practices for clinical decision support systems in computerized provider order entry systems. Gross PA, Bates DW.

4. PLoS Med. 2005 Sep;2(9):e255. Epub 2005 Sep 6. The effect of automated alerts on provider ordering behavior in an outpatient setting. Steele AW, Eisert S, Witter J, Lyons P, Jones MA, Gabow P, Ortiz E.
5. Am J Manag Care. 2006 Jul;12(7):389-95. Evaluation of laboratory monitoring alerts within a computerized physician order entry system for medication orders. Palen TE, Raebel M, Lyons E, Magid DM.

KEYWORDS: Patient safety, drugs, medication, computerized physician order entry, pharmacy transaction system, automated screening.

OSD08-H04 **TITLE:** Micro Games for Proactive Preventive Medicine

TECHNOLOGY AREAS: Human Systems

OBJECTIVE: To use computer gaming technology for medical training and learning

DESCRIPTION: The Department of Defense is aggressively pursuing unified Force Health Protection and Deployment Health strategies to protect Service members and their families from health hazards associated with military service. Toward that end, DoD is undertaking technology development programs that save lives and promote healthy individuals, units and communities while improving both force morale and warfighting capabilities. The operational force is exposed to health threats throughout the operational continuum, from CONUS fixed facilities (garrison, base, ashore) through deployment, employment, and redeployment. Developing and maintaining awareness of risks to health is a fundamental aspect of deployment operations. Advanced distributed learning, simulation-based training and computer game technologies would support proactive preventive medicine. While there are several “medical simulation” computer games available like ER Sim, 911 Paramedic, and Combat Medic: Special Operations, there are few examples of micro games pursuing this performance domain. A notable exception is Bac Attack a micro game that recently won the 2008 Game Design Challenge competition in San Francisco. Bac Attack pits man's strategic ingenuity against the march of armies of bacteria. Micro games can be very effective in engaging the learner, aiding in retention of information, and may be particularly appropriate learning strategies for individuals born during the digital age, digital natives (Prensky, 2001). Micro games are computer-delivered, learning simulations that are easy to access, are typically based on Adobe Flash, and last from five to 20 minutes. Micro games often include entertaining music and appealing graphics, but they also are educational and are perfect when individuals need to learn skills that can be taught through repetition (Aldrich 2007). Typical training strategies consist of the “tell-and-test” method with limited opportunities for practice. Retention of critical information is more likely to occur if the user is engaged, interacts, and training goals are clearly stated (Oblinger, 2006). This is particularly true in the case of task or procedural knowledge. The simplicity of micro games gives the user the ability to focus on content, rather than learning the intricacies of the game. They can easily be downloaded from the Internet and run from a variety of systems (computers, cell phones, personal digital assistants) allowing mobile E-learning anywhere / anytime. A web-enabled, training platform that provides didactic instruction and micro games for practicing conceptual and procedural knowledge acquisition would provide enormous training economy for proactive, preventative medicine. The technology challenge is to integrate didactic instructional materials with micro game practice environments in a web-enabled training platform. In order for the micro games to keep individuals up to date on changing or region-specific health and medical risks, an authoring system for both didactic materials and the micro game practice environment would add training agility and flexibility. Learning-centered design should also be considered as a guide for developing user interfaces. Tools should be based on existing medical and allied health knowledge, should be universally accessible, should allow for unlimited practice, and should be SCORM-compliant in content and in delivery modalities. Innovative and creative approaches to addressing technical goals are invited.

PHASE I: Research risks and feasibility associated with the development of micro gaming environment, generate a top-level design, and develop a proof-of-concept exemplar.

PHASE II: Develop, demonstrate, and field test a proactive and preventive health awareness training capability that optimally integrates didactic instruction within a micro gaming environment.

PHASE III DUAL USE APPLICATIONS: Prepare detailed plans for implementing demonstrated training

capabilities for applications in military and non-military, general populations. Phase III proposals must include a detailed market survey and letters of interest / commitment from potential commercial partners for evaluation of Phase III consideration.

REFERENCES:

1. Aldrich, C. (2007). Engaging Mini-Games Find Niche in Training: Quick, interactive simulations are meeting the training needs of businesses. Retrieved October 30, 2007, from <http://www.learningcircuits.org/2007/0707aldrich.html>
2. Oblinger, D. (2006). Simulations, Games, and Learning. Retrieved October 30, 2007, from <http://www.educause.edu/ir/library/pdf/ELI3004.pdf>
3. Prensky, M. (2001). Digital game-based learning (on-line version). New York: McGraw-Hill.

KEYWORDS: computer-based training, web-based training, , micro games, practice environments, proactive medicine, preventative medicine

OSD08-H05 **TITLE:** Determining Biomarkers of Occult or Emerging Disease for Predictive Modeling

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Provide occult infection biomarker(s), assessed clinically for association with outbreaks of disease, for forecasting outbreaks and their consequences.

DESCRIPTION: Members of the United States Armed Forces, overseas and domestically, face the threat of exposure to various weapons of mass destruction. In addition to traditional biological weapons, it is important to recognize and protect against future biological agents that can be weaponized from naturally occurring pathogens as well as genetically engineered pathogens. The 1996 outbreak of Bovine Spongiform Encephalopathy (BSE) and the discovery of a new strain of Creutzfeldt-Jakob disease (CJD) underscore the imminence and importance of addressing new human health hazards¹. New methods for rapid fieldable identification and detection of microbial pathogens are necessary in determining prevention strategies. The current state of the art to detect new outbreaks uses methods that have been used for nearly 100 years. They are generally laborious, slow, costly and only performed in a controlled laboratory setting. They are not well suited for rapid and accurate biosurveillance and are not considered fieldable systems for the warfighter. Recent outbreak discoveries encourage the development of new molecular methods for more rapid, sensitive and specific detection of known microbial pathogens.² With these emerging threats come the responsibility to determine real-time monitoring of threat agents and biomarkers or their presence that can be used for predictive modeling of disease outbreaks which is important for providing military commanders, homeland security, and public health officials with required information to protect against and prepare for outbreaks of new biological agents. Additionally, new methods could be used to identify novel, previously uncharacterized microorganisms and be automated and commercialized for use by hospitals and other clinical microbiology laboratories. While proven laboratory, non-fieldable methods are available for determining agent presence and biomarkers for well characterized pathogens we seek novel methods for the rapid determination of biomarkers in a fieldable system for occult or emerging diseases either naturally occurring or genetically engineered.

PHASE I: Develop laboratory tests for determining the presence of occult pathogen agents in culture samples, and determine best candidate for biomarker(s) which can be clinically determinable, match a disease that has sufficient epidemiological data for predictive modeling.

PHASE II: Provide sufficient data on the down selected disease-causing threat agent from Phase I to validate approach and methodology for detection and modeling. Demonstrate rapid identification of agent in fieldable assay method to allow modeling (algorithm) with real clinical data and develop an algorithm (software) that is at least specific to the example disease but can be generalized to others.

PHASE III DUAL USE APPLICATIONS: The developed model can be used by military and civilian health

officials to determine biomarkers for occult or emerging diseases. Additionally, the commercial sector could use such a model for preparing for possible outbreaks of emerging diseases.

REFERENCES:

1. Bastian, Frank O., "Late Breaker—Prions, Bovine Spongiform Encephalopathy (Mad Cow Disease) on Human Health Risk," 1996 Richard J. Duma/NFID Annual Press Conference and Symposium on Infectious Diseases, 1996.
2. Relman, David A., "New Methods for Identification and Detection of Microbial Pathogens," 1996 Richard J. Duma/NFID Annual Press Conference and Symposium on Infectious Diseases, 1996.

KEYWORDS: occult disease, emerging disease, biomarkers, forecasting outbreaks, predictive modeling, infectious disease, biological weapons, biological agents

OSD08-H06 **TITLE:** Interactive Cognitive Interface and Health Monitoring System

TECHNOLOGY AREAS: Human Systems

OBJECTIVE: To develop an interactive, low cost, effective cognitive interface to support soldiers living with minor cognitive impairments due to injuries such as Traumatic Brain Injury and Post Traumatic Stress Disorder. This system should focus on supporting some activities of daily living and provide assistance in self health maintenance.

DESCRIPTION: Reminding systems can help soldiers live independently while coping with injuries such as Traumatic Brain Injury and Post Traumatic Stress Disorder. Soldiers with such injuries may be high functioning in some aspects of life but require a compensatory strategy for performing activities of daily living. Reminding systems that use advanced Artificial Intelligence techniques such as Autominder (Pollack, 2006) can be deployed in concert with low cost sensing devices to create a proactive and adaptive self health monitoring and independent living system.

However, creating a scalable and reliable system requires computational capabilities beyond what is available today. A high number of sensors necessitate a degree of computing power that challenges cost-effectiveness, while a low sensor count provides insufficient granularity. Innovative solutions will support regular but unobtrusive interactions with the system, thus increasing its accuracy and acceptance. Psychosocial aspects of health provider and patient interaction such as trust and affect have been shown to change treatment outcomes. Augmenting trust between human users and machines has also been shown to influence the combined system performance. Techniques used in building computational social agents (Miller, 2004) can be employed to encourage meaningful human-system interactions that yield information about a soldier's physical and emotional health. The resulting data can then be reviewed by the soldier and human caregivers to evaluate health status and detect the potential onsets of problems. The user interface component must be flexible to include a number of form factors and modalities so it can be customized to the abilities of the human user. The human-system interactions may also be refined over time as the system develops the user model. The resulting system must have the ability to evolve with the human user as his/her needs change and keep the interest of the user so it can be a long-term aid.

PHASE I: Development of an initial plan and concept design for the overall system. Illustrate and storyboard the proposed system, provide usage scenarios, and create a walk-through of a prototype.

PHASE II: Implement a prototype and conduct a study to evaluate its usability.

PHASE III: The described system can be used by both civilian and military/veteran populations with cognitive disabilities such as dementia or moderate Traumatic Stress Disorder.

REFERENCES:

1. Pollack, M. E. (2006). "Autominder: A Case Study of Assistive Technology for Elders with Cognitive Impairment," *Generations: The Journal of the American Society on Aging*, 30(2):67-69, 2006.
2. Miller, C. (Guest Ed.) (2004). "Human-Computer Etiquette: Managing Expectations with Intelligent Agents."

Communications of the Association for Computing Machinery. 47(4), April. 30-3.

KEYWORDS: Cognitive, system, monitor.

OSD08-H07 TITLE: Automated Knowledge Structuring of Medical Charts Data

TECHNOLOGY AREAS: Information Systems

OBJECTIVE: To develop a software solution for structuring and examining both individual and aggregated medical data in real or near real-time to identify etiologic factors of health changes or emergent events.

DESCRIPTION: Medical charting is the primary source of communication between care providers and is the most comprehensive repository of medical history of a patient. However, it is labor intensive to extract knowledge from medical charts both at the individual and the aggregated level due to the lack of unified structure in medical data, yet flexibility such as the use of narrative style is necessary for care providers. While experienced medical personnel may be able to quickly identify information pertinent to the patient's current condition, substantial effort is required to make this data machine readable for useful applications such as statistical analysis. Beyond electronic versions of paper charts, what is needed are methods of recording and structuring medical data so the process maintains its flexibility to fit into the work flow of care providers but the resulting format is compatible with computational analysis. This method must be scaleable so large amounts of data can be processed in order to detect items such as commonalities among multiple patients, but should not significantly increase the workload of medical personnel. A software toolset is required for a number of tasks, including the collection of data, the authoring of evaluation criteria and the evaluation of medication data. The software for data input may be PDA based and can include annotation tools that allow the human user to highlight keywords or phrases in real time and link them to a larger knowledgebase or other related records. The ability to quickly run data filters over a consolidated set of medical charts can "raise red flags" and draw attention to anomalies used to help identify the onset or origin of disease outbreaks or precipitating factor for health status changes, functionally acting as diagnostic decision aids. The ability to trace results back to the original individual medical cases is vital to such investigations, as are tools for evaluators to create and edit filters so data can be evaluated in real or near real-time. It should also be possible to create data filters a priori for known warning signs. Such a toolset will allow a longitudinal view (pre-, during, and post-deployment) of individual soldiers' records as well as a latitudinal view of health status across multiple soldiers.

PHASE I: Development of a concept plan, concept design for the overall system and a simple prototype. In the concept plan, illustrate and storyboard the proposed toolkit. Outline its limitations and risks, and define an implementation plan.

PHASE II: Implement a prototype and conduct a study to evaluate its usability.

PHASE III: For military applications, the capabilities developed under this effort could be used in conjunction with current medical records systems to bridge the information gap between pre- and post-deployment. The described system can be also used by a variety of care providers in non-military applications, from emergency response to elder care.

REFERENCES:

1. Camacho, A., (2005), Environmental Surveillance: Key Role In Protecting Troops' Health, Deployment Health Quarterly, 9-10 Spring 2005.
http://fhp.osd.mil/fhp_online/archives/spring05.pdf

KEYWORDS: Medical charts, software, health status, data.

OSD08-H08 TITLE: Augmented Reality Systems for Training Health Care Providers

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: The objective of this research is to develop and validate prototype augmented reality (AR) simulations for both initial and sustainment training of life saving skills. The primary focus are the three main causes of trauma death which are hemorrhage, improper airway management, and tension pneumothorax. The training audience for these simulations are combat medics and combat life savers in the military and their civilian counterparts which include EMTs and other first responders.

DESCRIPTION: This project falls into the category of developing and maintaining skills among the personnel of the Military Health System. We are looking for innovative ideas that combine aspects and recent advances in immersive reality technologies with those of mannequin or actor-based systems, e.g., standardized patients. Generally we are seeking innovative technologies and/or approaches that enable superimposing of virtual or real images of external or internal trauma injuries onto either a mannequin or an individual acting as a patient. The training system should focus on the three main causes of trauma deaths, i.e., hemorrhage, improper airway management and tension pneumothorax.

We seek tools that:

- (1) engage the user(s) in a compelling, realistic simulation experience;
- (2) render and properly size and register the visual images on the mannequin or patient actor;
- (3) allow for interaction between the care giver and the mannequin / actor;
- (4) rapidly convert Magnetic Resonance Imaging (MRI) or other source data into visual formats that can be run on standard Image Generator (IG) systems;
- (5) explore the use of intelligent tutoring systems capability;
- (6) identify metrics upon which to base trainee performance;
- (7) monitor patient/casualty vital signs;
- (8) based on identified metrics, monitor and assess care givers' performance;
- (9) can be an individual or team trainer

PHASE I: Perform a feasibility study and analysis and develop a concept definition for the AR simulator system. The study will identify the technical risks associated with the approach. The study will identify both the innovative technologies and approaches proposed as well as the costs and schedule associated with development and demonstration of the prototype.

PHASE II: Develop and demonstrate a functional prototype of the augmented reality system that supports treatment of at least one of the three major types of injuries. This initial demonstration will be on a stationary mannequin.

PHASE III: DUAL-USE COMMERCIALIZATION. The focus will be on commercializing a training system that is producible and affordable for both military and civilian sectors. The system shall be expandable to include treatment of all three types of major injuries.

REFERENCES:

1. Scaletta, T. Subdural Hematoma, <http://www.emedicine.com/EMERG/topic560.htm>
2. Price, Daniel D. Epidural Hematoma, <http://www.emedicine.com/EMERG/topic167.htm>
3. Bowen, T.E., Bellamy, R. Emergency War Surgery, U.S. GPO 1988.
<http://www.vnh.org/EWSurg/EWSTOC.html>
4. Sim, Patrick Web Based Craniotomy Simulator: <http://www.scs.leeds.ac.uk/vis/patrick/>
5. Agus, Marco, Bettio, F., et al Real and Virtual Surgical Procedures on the Temporal Bone, Presented at: IEEE Virtual Reality Conference, Conference held in Los Angeles, CA, USA, March 22-26, 2003.
<http://www.crs4.it/vic/cgi-bin/multimedia-page.cgi?id='104'>
6. Jha, Ashish K., Duncan, Bradford W., Bates, David W. Simulator-Based Training and Patient Safety.
<http://www.ahrq.gov/clinic/ptsafety/chap45.htm>

7. Satava, Richard M., Advanced Simulation Technologies for Surgical Education; American College of Surgeons
<http://www.facs.org/about/committees/rci/81777.html>

8. Liu, A., Cotin, S., et al MICCAI 2003 Tutorial: Simulation for Medical Education,
<http://www.simcen.org/miccai2003/index.php>

KEYWORDS: medical simulation system, augmented reality; standardized patient; combat casualty care; medical training; simulation; trauma; military medicine; surgical skills training, mannequin

OSD08-H09 **TITLE:** Advanced Distributed Learning in Support of the Maintenance of Certification (MOC) of Surgical Skills

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To design, develop, demonstrate and validate a prototype web-based instructional system that supports Maintenance of Certification (MOC) of surgical skills.

DESCRIPTION: There is an increasing need for specialty surgeons, especially those in the military and in a deployed status, to maintain their specialty skills. This includes specialty surgeons in the Military Health System, to include active duty, guard, and reserve health care personnel. We are looking for innovative ideas that employ advanced distributed learning to enable surgical personnel to maintain, even increase, clinical knowledge and skills within their specialty while deployed for extended periods of time during which they may not have the opportunity to practice the cognitive or psychomotor skills of their surgical specialty.

We seek a solution that:

- 1- delivers clinical content based on a current surgical curriculum that has been approved by the professional society of the surgical specialty chosen, e.g., for orthopaedics, the society is the American Academy of Orthopaedic Surgeons (AAOS).
- 2- can be hosted on either standard Personal Computer (PC) desktop or notebook, tablet PC, and/or Personal Digital Assistant (PDA) displaying a range of pixel resolutions.
- 3- engages the user in an engaging learning experience;
- 4- is Shareable Content Object Reference Model (SCORM) compliant in content and delivery modalities.
- 5- contain either video clips of actual procedures or validated computer generated images of procedures.
- 6- employs intelligent tutoring systems that monitor the students' progress and adapt the lesson plans to match the current proficiency.

PHASE I: Perform a feasibility study and develop a concept definition of the system.

PHASE II: Develop and demonstrate the prototype system based on at least one surgical specialty, then conduct a training effectiveness study of the prototype to determine transfer effectiveness.

PHASE III: DUAL-USE COMMERCIALIZATION. The focus will be on commercializing the system. This capability will provide an immediate, increased capability through out the military and civilian medical communities as it can be used as an instructional mechanism for both initial and sustainment training.

REFERENCES:

1. SCORM-accessed at <http://www.adlnet.gov>
2. Cybercare: Virtual Reality Technologies for Homeland Defense, by Eliot Grigg, et al, in "Medicine Meets Virtual Reality 11: NextMed: Health Horizon", pp 96-99, J.D. Westwood, et al, Eds. IOS Press, Amsterdam, 2003.

KEYWORDS: Maintenance of Certification, medical simulation, surgical simulation, advanced distributed learning, ADL, medical skills training, performance assessment, intelligent tutoring

TECHNOLOGY AREAS: Materials/Processes, Biomedical, Human Systems

OBJECTIVE: The objective of this effort is to develop diamond-like carbon coatings (DLC) that can be applied to transparent polymers, mainly polycarbonate, currently being used for Soldier's anti-ballistic protection. These devices include faceshields, eye glasses and protective mask inserts. The diamond-like coating will provide increased strength, enhanced anti-ballistic capabilities and greatly improve scratch and abrasion resistance.

DESCRIPTION: Data shows a dramatic increase in Soldier trauma in OIF/OEF occurs to the head, face and eyes. The reasons for this increase include better body armor that protects the trunk and decreases the percentage of trauma to those regions and the use of improvised explosive devices makes the head and neck region more vulnerable. Currently, eye protection is generally limited to user provided Wiley XTM polycarbonate sunglasses, BLPS or safety glasses. These and other brand safety glasses meet or exceed ANSI Z87.1 safety standards however; they provide very limited high kinetic energy ballistic protection against projectiles that are generally created by improvised explosive devices. The polycarbonate is also easily scratched in the abrasive, sandy environments of Iraq and Afghanistan, limiting their life expectancy and obstructing full vision. Diamond-like coatings have been applied to metals for years to increase scratch resistance, function as a solid lubricant to decrease frictional wear and protect against corrosion. Many razor blades have diamond-like coatings for these reasons. The application of diamond-like coatings to metals generally requires the substrate's temperature be between 600-1000 degrees C during the application process, far above the glass transition and melting temperature for commonly used transparent polymers. The ability to apply a diamond-like coating to a polymer, especially a transparent polymer, would tremendously increase all these properties in the polymer, as well as add strength and increase anti-ballistic protection. The coating must have sufficient bond strength, either chemical or mechanical or both, to the underlying polymer such that spontaneous separations do not occur. The diamond-like coating must have to have a refractive index similar to the polymer so vision would not be distorted when looking through it and meet ANSI Z80.3 optical standards. To be useful, the diamond-like coating must be able to be applied to a curvilinear polymer sheet, approximately 4" in height and 8" in width. The ability to coat safety lenses in glasses and chemical protection mask eye inserts would be a tremendous improvement to currently available materials.

PHASE I: Determine the feasibility of depositing a diamond-like coating onto polymeric surfaces, not restricted to but MUST include transparent polymers, in a manner that does not destroy the integrity of the polymeric substrate. Feasibility includes the ability to deposit, characterize, test mechanical properties and measure adhesion to underlying substrate.

PHASE II: Required Phase II deliverables include a demonstrable technique to deposit a diamond-like coating on large (4" X 8"), curvilinear polymer substrates, safety glass lenses and chemical protective mask eye inserts. This technique should be such that it lends itself to affordable mass production. The technique should not be so complex and variable so as to prevent predictable manufacturing processing. There is no restriction to the types of polymer chosen but transparent polycarbonate must be one of those selected. Development of prototypes that demonstrate the potential applications of this technology will be considered success. Proof of meeting or exceeding ANSI Z87.1 and Z80.3 must be provided. Adequate bonding between the diamond-like coating and the underlying polymer at all temperatures encountered during deployments (-20 to 140 degrees F) must be demonstrated. Scratch resistance over the entire polymer surface must be demonstrated

PHASE III: The ability to place diamond-like coatings on polymers and produce stronger, scratch-resistant and corrosion resistant faceshields, safety glasses and protective mask eye inserts would provide tremendous value added to the US Army, both in terms of individual Soldier protection and in cost savings by not having to replace scratched and broken polymers. In commercial eye glass production, it would allow production of light weight polymeric glass lenses with higher scratch resistance than traditional heavy glass lenses. The ability to apply a very low friction solid lubricant to polymeric components that are subject to frictional wear, i.e. gears, would dramatically increase the life expectancy of that component. This would save large amounts of money both in a military setting as well in a commercial, civilian setting. Twenty of both the final coated and uncoated 4" X 8" polymer substrates will be provided to USADTRD for future ballistic testing.

REFERENCES:

1. Trauma Data Registry, Institute of Surgical Research, San Antonio, TX.
2. Bunker, BC et al: Ceramic Thin-Film Formation on Functionalized Interfaces Through Biomimetic Processing, *Science*, 264:48-55, 1994.
3. Yang, ES: *Fundamentals of Semiconductor Devices*, McGraw-Hill, Inc., New York, 1978.
4. Popovici, G; Prelas, MA: Nucleation and Selective Deposition of Diamond Thin Films; Presented as an invited paper at the Diamond and Diamond-Like Films Workshop, International Society for Hybrid Microelectronics, March 29-31, 1992, Breckenridge, CO.
5. Celi, FG; White, D; Purdes, AJ: Deposition of Smooth, Oriented Diamond Films Using Microwave Plasma Chemical Vapor Deposition, *Thin Solid Films*, 212:140-149, 1992.
6. Butler, JE; Woodin, RL: Thin Film Diamond Growth Mechanisms, *Phil. Trans. R. Soc. London*, 342:209-224, 1993.

KEYWORDS: Diamond-like coatings, polymeric coatings; anti-ballistic polymers, scratch resistant coatings